REMARKS

Claims 11, 45, 47-52, 57, 58 and 60 are pending in this application. Claims 44, 46, 53-56 and 59 have been cancelled. New claim 60 is added and claims 11, 47 and 50 are amended. Support for the new claim and the amendments can be found throughout the specification at, e.g., page 5, lines 13-17; page 15, lines 16-21; page 35, lines 9-20; and the original claims. The new claim and amendments made herein add no new matter.

Claim Objections (Informalities)

At page 3 of the Office Action, claim 11 was objected for reciting "one or-more ancillary reagents" and claim 50 was objected to for reciting "an Fab fragment, an Fab fragment" (Underlining in the original). Claim 11 has herein been amended to "one or more ancillary reagents" and claim 50 has been amended to "an Fab fragment, an Fab' fragment." As acknowledged by the Office Action, such amendments render the claim objections moot.

Rejection Under 35 U.S.C. §103 (Obviousness)

At pages 4 and 5 of the Office Action, claims 11, 44-48, 57, and 58 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Lind et al. (U.S. Patent No. 6,084,075) in view of Hardiman et al. (U.S. Patent No. 7,115,379). In addition, at pages 5 and 6 of the Office Action, claims 49-52 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Lind et al. (*supra*) and Hardiman et al. (*supra*) as applied to claim 11, and further in view of Lam et al. (U.S. Patent No. 6,171,586).

According to the Office Action,

> it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a kit comprising the anti-CCR2 antibodies disclosed by Lin [sic] et al, one or more ancillary reagents suitable for detecting the presence of an antibody-antigen complex taught by Hardiman et al, and to include antigen-binding fragments Fv, Fab, Fab', and $F(ab')_2$, recombinant antibodies such as humanized and human antibodies in the kit with a reasonable expectation of success. (See Office Action at page 6).

Applicants respectfully traverse these rejections and submit the following remarks to show that the claims are non-obvious in view of the cited references.

Claim 11, and the claims dependent therefrom, is drawn to a test kit for use in detecting the presence of a mammalian CC-chemokine receptor 2 in a biological sample. The test kit comprises: a) an antibody or antigen-binding fragment thereof which binds to the amino-terminal domain of a mammalian CC-chemokine receptor 2, wherein said antibody or antigen-binding fragment thereof inhibits binding of a chemokine to the receptor and inhibits one or more functions associated with binding of the chemokine to the receptor; and b) one or more ancillary reagents suitable for detecting the presence of a complex between said antibody or antigen-binding fragment thereof and said mammalian CC-chemokine receptor 2 or a portion thereof.

First, Applicants respectfully submit, and the Office Action acknowledges, that the teaching of Lind et al. "differs from the claimed invention by not describing a kit comprising anti-CCR2 antibody and one or more ancillary reagents suitable for detecting the presence of complex between antibody or antigen binding fragment thereof and mammalian CCR2, and the antibody being lyophilized." (Underlining in the original; see Office Action at page 4). However, the Office Action believes that Lind et al. "teach neutralizing monoclonal antibodies MCPR-04, MCPR-05, and MCPR-06 that bind to human CCR2 and bock chemokine MCP-1 binding and MCP-1 activities." (See Office Action at page 4).

Lind et al. do disclose antibodies that bind to CCR2. Some of the antibodies disclosed by Lind et al. (antibodies MCPR-03, MCPR-04, MCPR-05, and MCPR-06) were derived from mice immunized with KLH-coupled peptides corresponding to the third extracellular loop (amino acids 273-292) of CCR2. Thus, these antibodies clearly do not satisfy the requirements of the claims, e.g., that an antibody bind to the amino-terminal domain of a mammalian CCR2.

The remaining antibodies disclosed by Lind et al. (MCPR-01 and MCPR-02) were derived from mice immunized with KLH-coupled peptides corresponding to the amino terminal domain (amino acids 24-38) of CCR2. (See Lind et al. at column 14, Table III). In Table III, Lind et al. provide a summary of the specificities and activities of MCPR-01 and MCPR-02. MCPR-01 is disclosed to be neither agonist nor antagonist of MCP-1-induced calcium influx or transmigration, whereas MCPR-02 is disclosed to be an agonist of calcium influx and transmigration. (See Lind et al. at Table III). Therefore, it is clear that Lind et al. do not disclose

or suggest any antibodies that bind to the amino terminal domain of a mammalian CCR2, inhibit the binding of a chemokine to the receptor, and inhibit one or more functions associated with the chemokine receptor, as required by the claims.

Neither Hardiman et al. nor Lam et al. cure the aforementioned deficiencies of Lind et al.

The Office Action states that "Hardiman et al. teach that reagents for diagnostic assays are frequently supplied with kits" and "further teach a kit comprising antibodies or antigen binding fragment thereof to CX3Ckine receptor, the label, buffer, stabilizer, and materials necessary for signal production." (Underlining added; see Office Action at page 4). However, contrary to the above characterization, Applicants respectfully point out that Hardiman et al., as cited by the Office Action, disclose kits containing antibodies specific for a chemokine (i.e., CX3Ckine), not a chemokine receptor such as a mammalian CCR2, as required by the claims. For example, Hardiman et al. state that

> [a] preferred kit for determining the concentration of, for example, a CX3Ckine in a sample would typically comprise a labeled compound, e.g., receptor or antibody, having known binding affinity for the CX3Ckine ... Antibodies, including antigen binding fragments, specific for the CX3Ckine or ligand fragments are useful in diagnostic applications to detect the presence of elevated levels of CX3Ckine and/or its fragments." (Underlining added; see Hardiman et al. at column 36, lines 4-16).

Lam et al. disclose stable aqueous pharmaceutical formulations comprising a therapeutically effective amount of an antibody not subjected to prior lyophilization. (See Lam et al. at, e.g., column 2, lines 25-28). At columns 9 and 10, Lam et al. states that "the antibody is directed against an antigen of interest," although, of the dozens upon dozens of "antigens of interest" recited in column 10, there is no mention or even a suggestion of a mammalian CCR2. (See Lam et al. at, e.g., column 9, lines 59-65 and column 10, lines 5-63). Thus, it is hard to imagine how Lam et al. disclose antibodies that bind to the amino terminal domain of a mammalian CCR2, inhibit the binding of a chemokine to the receptor, and inhibit one or more functions associated with the chemokine receptor, let alone test kits comprising an anti-CCR2 antibody and one or more ancillary reagents suitable for detecting the presence of complex between antibody or antigen binding fragment thereof and mammalian CCR2.

Therefore, since none of the cited references, alone or in combination, teach or suggest antibodies that possess the structural and functional characteristics required by the claims or kits

containing such antibodies and one or more ancillary reagents, the references do not render the claims obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

CONCLUSION

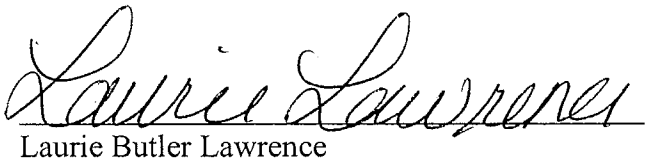
For the reasons set forth above, applicants submit that all grounds for objection and rejection have been overcome and that all of the pending claims are now in condition for allowance, which action is earnestly requested. Applicants do not accede to any positions of the Examiner not specifically addressed above.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at the number provided below.

The fees for the Petition for a three (3)-month Extension of Time are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 10448-215011.

Respectfully submitted,

Date: 10/12/07



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